K113440

MAY 23 2012

510 (k) Summary
NITRILE EXAM GLOVES, POWDER FREE, BLACK

1.0	**Submitter's Name**	:	Central Medicare Sdn. Bhd.
2.0	**Submitter's Address**	:	PT 2609-2620 Bt 8, Jalan Changkat Jong Mukim Changkat Jong 36000 Teluk Intan, Perak Malaysia.
3.0	**Telephone No.**	:	605-6231220
4.0	**Fax No.**	:	605-6231230
5.0	**Contact Person**	:	Mr. K. F Cheong
6.0	**Date of Preparation**	:	18th Nov 2011
7.0	**Name of Device**	:	Nitrile Exam Gloves, Powder Free, Black

Size	Model Number
Small	N641
Medium	N642
Large	N643
Extra Large	N644
Extra X-Large	N645

Proprietary/Trade Name	:	Nitrile Exam Gloves, Powder Free
	:	Other clients private labeling
Common Name	:	Nitrile Examination Glove
Classification Name	:	Patient Examination Glove
Device Classification	:	I
Regulation Number	:	21 CFR 880.6250
Product Code	:	LZA

8.0 Identification of The Legally Marketed Device:

The Nitrile Exam Gloves, Powder Free, Black Class I patient examination gloves, Nitrile-80 LZA, meets all of the requirements of ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

Predicate device: Blue Nitrile Examination Gloves, Powder Free (K093696)
Powder Free Nitrile Examination Gloves White Colored (K103734)

9.0 Description of Device:

The Nitrile Exam Gloves, Powder Free, Black, Class I patient examination gloves, Nitrile-80 LZA, will meet all the current specification for ASTM D6319-10.

10.0 Intended Use of the Device:

A powder free Nitrile Examination glove is a disposable device made of synthetic material that is worn on the hand for medical purposes to prevent contamination between patient and examiner.

11.0 Summary of The Technological Characteristics of New Device Compared to The Predicate Device:

There is no different technology characteristic. Gloves are made from nitrile compound (dispersion of butadiene acrylonitrile copolymer) and the initial products are powder free nitrile examination gloves.
The Nitrile Exam Gloves, Powder Free, Black possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D 6319-10	Meets
Physical Properties	ASTM D 412-98 (Reapproved 2002)	Meets
Freedom From pin-holes	ASTM D 5151-06	Meets
Powder Free Residue	ASTM D 6124-06	Meets
Biocompatibility	Dermal Sensitization in the guinea pig (as per ASTM F 720-81(Reapproved 2007))	Passes Not a Dermal Sensitization
	Primary Skin Irritation Test in rabbits (as per Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 & 1500.41)	Passes Not a Primary Skin irritant

12.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Testing performed per ASTM D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application and 21 CFR 800.20. Gloves meet all the current ASTM D 6319-10.

Primary skin irritation testing in the rabbit and delayed dermal contact sensitization study in the guinea pigs indicate no irritation or sensitization.

13.0 Brief description of Clinical Tests

No new clinical tests were conducted under this 510(k).

14.0 Conclusions Drawn from the Non-Clinical and Clinical Tests.

It can be concluded that the Nitrile Exam Gloves, Powder Free, Black meet the ASTM standard or equivalent standard and FDA requirements for water leak test on pinhole AQL, meet labeling claims. It is as safe as effective, and performed as well the legally marketed indentified in clause 8.0.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Central Medical Sdn Bhd
C/O Mr. Nicholas Wang
Senior Vice President
Encompass Medical Supplies
1930 Brea Canyon Road #240
Diamond Bar, California 91765

MAY 23 2012

Re: K113440
Trade/Device Name: Nitrile Powder-Free Black Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 17, 2012
Received: April 20, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant : Central Medicare Sdn. Bhd.

510(k) Number (if known): K113440

Device Name: Nitrile Exam Gloves, Powder Free, Black

Size	Model Number
Small	N 641
Medium	N 642
Large	N 643
Extra Large	N 644
Extra X-Large	N 645

Indication For Use: A powder free Nitrile Examination glove is a disposable device made of synthetic material that is worn on the hand for medical purposes to prevent contamination between patient and examiner.

Prescription Use _____ **AND / OR** **Over-The-Counter Use** _____X_____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113440